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VIEWPOINT

The importance of insulin donations for children in 43 low- and middle-income countries

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Abstract

Diabetes mellitus is rapidly becoming one of the major diseases affecting people's health globally. Over half of 100 million diabetes patients who need insulin to survive, especially in low- and middle-income countries (LMIC), are not able to get this medicine and die prematurely. Since 2000, insulin-producing companies have started support programmes with a component of insulin donations to children and youth with type 1 diabetes in 43 LMIC. Based on their experiences we conclude, contrary to common belief, that the diagnosis, treatment, and prevention of fatal complications in children with type 1 diabetes in LMIC are very possible in practice, with large improvements in survival, mean body weight, mean glucose levels, and frequency of complications. Medicine donations can never offer a sustainable solution and we now propose a ten-step transition process towards a fully sustainable national diabetes care and prevention programme for children and youth with diabetes type 1.

Keywords Diabetes type 1 · Children · Insulin · Medicine donations · Low- and middle-income countries · Essential medicines · Pharmaceutical companies

Introduction

Diabetes mellitus is rapidly becoming one of the major diseases affecting people's health globally. The World Health Organization (WHO) estimates that the prevalence among adults above 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014; this rise has been even more rapidly in low- and middle-income countries (LMIC). Diabetes is currently the seventh leading cause of death, with almost all deaths occurring before the age of 70 [1]. For about 100 million people

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living with diabetes worldwide, daily injections with insulin are essential to prevent premature death and a host of debilitating and potentially fatal complications, such as hypo- and hyperglycaemia, diabetic coma, cardiovascular disease, renal failure, gangrene of extremities, and blindness. However, more than half of them cannot obtain or afford this life-saving medicine, especially in LMIC [2]. Three-quarters of people living with diabetes are of working age, and the regular supply of insulin therefore offers an important opportunity to improve health at the population level.

The situation is especially dramatic in the case of insulin-dependent diabetes ('diabetes type 1'), which usually manifests itself in teenaged children. In view of the organizational and financial complexities of recognizing the disease, teaching and supporting the patients and their parents, and fulfilling the daily need of injectable insulin and some basic diagnostics to measure blood glucose levels, in many LMIC the diagnosis and treatment of diabetes type 1 is not seen as a priority for health systems that are already overburdened; most patients and parents are simply left on their own. Although exact figures are lacking, a study published in 2016 estimated that, in the absence of daily insulin treatment, the average survival of children and youth with type 1 diabetes is less than 1 year [3]; most untreated patients succumb to the fatal complications of the disease and very few of them reach adulthood.

Three pharmaceutical companies, Novo Nordisk, Eli Lilly and Company, and Sanofi, produce 92–93% of all insulin consumed in the world [3]. While these companies maintain high prices in industrialized countries such as the United States (US), and in most LMIC, in the last two decades they have also established support programmes to promote access to insulin for poor and disadvantaged patients in LMIC. To do so they often work through separate foundations such as the International Diabetes Federation (IDF) and the World Diabetes Foundation (WDF). The impact of these donations has never been systematically assessed and published in the peer-reviewed literature.

In this Viewpoint, we argue that these insulin donations have now delivered the proof of concept that, contrary to common belief, diagnosis and treatment of type 1 diabetes and the prevention of complications are very possible in LMIC. We also argue that these programmes can play a 'pathfinder' role in countries where the public sector is currently unable to provide insulin and where high prices in the private sector make insulin unaffordable. Finally, we present a ten-step process to transfer the responsibility for diabetes prevention, care and treatment for children and youth from a donor-supported programme towards a national system of social security or health insurance.

From looking at the little publicly available information from relevant websites, annual reports and press releases, conference presentations, the published and grey literature, and discussions with experts from international NGOs (WDF, IDF, Life For A Child (LFAC)] and national programmes (e.g. Cameroun, Guinea, Mali, Nigeria, Senegal, Tanzania), we make the following observations:

Few company-supported programmes include a component of donated insulin

We identified more than 40 different company-supported programmes for type 1 and 2 diabetes education, prevention, diagnosis, treatment, and care in over 70 LMICs [4–13]. The IDF collaborates with 230 national diabetes organizations in 170 countries, and the WDF website lists nearly 400 separate partnerships in 117 countries [13]. Most of these projects focus on advocacy, prevention, screening, training of patients and health workers, establishment of treatment centres, supply of equipment, and mobile clinics [14]. Few programmes include a component of donated insulin.

In 2001, the IDF launched the Life For A Child (LFAC) programme [15] to support children and youth with diabetes in the developing world with human insulin, syringes, blood glucose monitoring equipment, education materials, health worker training, treatment guidelines, research, infrastructure, capacity building, and vocational training. Eli Lilly is the main supplier of free insulin and their largest donation is for this programme [16, 17]. In 2009, Novo Nordisk launched the Changing Diabetes® in Children (CDiC) programme to improve delivery of care to children and youth with type 1 diabetes in resource-poor settings, supplying donated insulin [18, 19]. In 2010, Novo Nordisk also started the Base of the Pyramid project, targeting the working poor in four LMIC by developing scalable, sustainable, and profitable solutions to increase diabetes care [20]. The WDF has facilitated some time-limited donation programmes in a few additional countries.

The number of children and young adults receiving donated insulin is increasing

From 2009 to 2015, the programmes with a component of free insulin covered 43 LMICs [14], and focused on children and young adults with type 1 diabetes (Table 1). The estimated number of children and young adults benefitting from insulin donations rose from 8193 in 2009 to 35,382 in 2015 (Fig. 1). Several countries

Table 1 Country programmes with a component of donated insulin for patients with type 1 diabetes (2009–2015)

Africa Burkina Faso[a], Burundi[a], Cameroon[b,c], Congo[a], Congo DR[a,b,c], Eritrea[a], Ethiopia[a,b,c], Ghana[a], Guinea[c], Kenya[a,b,c], Mali[a], Mauritania[a], Nigeria[a,b], Rwanda[a], Sudan[a,b], Tanzania[a,b,c], Togo[a], Uganda[b,c], Zimbabwe[a]

Americas Bolivia[a], Cayman Islands[a], Dominican Republic[a], Ecuador[a], Guatemala[a], Guyana[a], Haiti[a], Jamaica[a], Mexico[a]

Asia/Oceania Azerbadjian[a], Bangladesh[a,c], Cambodia[a], China[b], Fiji[a], India[c], Maldives[a], Nepal[a], Pakistan[a,b], Papua New Guinea[a], Philippines[a], Solomon Islands[a], Tajikistan[a], Uzbekistan[a], Vietnam[a]

[a]Life For A Child

[b]World diabetes foundation

[c]Changing Diabetes in Children

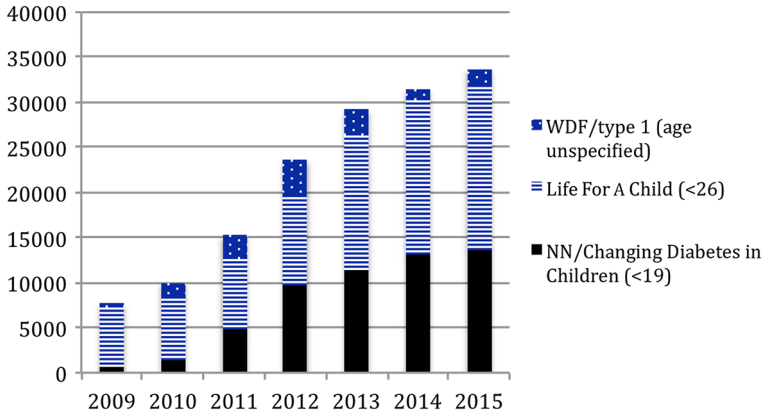

Fig. 1 Estimated number of patients with type 1 diabetes benefitting from donated insulin, in 43 low- and middle-income countries (2009–2015)

showed dramatic increases in the number of patients covered. In Rwanda, the programme started with 25 patients in 2004 and included 699 patients in 2014 [21]. Tanzania [22, 23] started with 50 registered patients and participation rose to 2116 in 13 years; Mali [24] from 7 to 53 patients in 9 years, and Guinea [25] from 44 to 448 patients in 4 years.

Most programmes also report large increases in the number of diabetes treatment centres. Rwanda increased facilities with such programmes from 10 in 2009 to 40 hospitals in 2014 [21]. The programme in Tanzania started with one diabetes clinic in 2003 and has recently extended to 187 district hospitals [22]. In Guinea, the programme grew from nine hospitals in 2009 to 64 hospitals in 2013 [25], and in Cameroun from two centres in 2010 to 9 centres in 2015, covering all but two provinces [26]. Twenty LFAC country programmes now claim near-universal national coverage of children with type 1 diabetes [27].

Globally, there are about 542,000 children under 15 years of age with type 1 diabetes and LFAC estimates that 112,000 of them are in need of support [15]. Our estimated number of about 35,000 patients up to the age of 25 years who benefitted from donated insulin in 2015 therefore represents only a small part of the global need.

Donation programmes lead to better health outcomes

So far, only ten country programmes have reported data on the health impact of treatment with donated insulin [14]. In Cameroon [28], Northern India [29], and Rwanda [30] the average body weight and/or body mass index increased from 4 to 23% over 3 years. In Cameroun [28], mortality from diabetes-related causes decreased from an estimated 80% without insulin treatment to about 10% after 5 years of treatment. In Rwanda, mortality of registered patients was 6.2% after 5 years and 17.5% after 10 years of treatment [21, 30]; Tanzania [22] and Guinea [25] had similar results.

The median value of the mean HbA1c (a measure of the average level of blood glucose over the last 2 to 3 months) of new patients entering the support programmes

was 11.5% (range 10.3–14%). The median reported value after 1–3 years of treatment was 8.4% (range 7.9–9.8%), and 9.5% (range 8.2–10.43%) after 6–8 years. The largest reductions usually appeared in the first year of treatment. Overall, the proportion of patients with high HbA1c values (> 11%) decreased from 72 to 50% in Tanzania [23] and from 30.8 to 9% in Rwanda [21]. The frequency of serious complications also decreased: among 104 patients in Cameroon [26, 28] the annual frequency of serious hypoglycaemia reduced from 26 to 14.4%, and serious ketoacidosis from 29.8 to 6.7% over 5 years. In Tanzania [23], serious ketoacidosis decreased from 10 to 0.6%.

The Nepal programme reports that 90% of treated children attend school 'normally' (likely meaning regularly and with reasonable results) [31] and in Guinea delayed puberty and delayed growth decreased [25]. Yet in Ghana [32], Haiti [33], and Tanzania [23] only half the children and youth attend school regularly, and in Haiti [33] 92% attend a grade level inappropriate for their age. In Tanzania, 32.6% missed school and three-quarters showed poor performance [23].

Thus, the health impact of donation programmes is positive when compared with the certain death the children would otherwise have faced. Yet treatment often remains partially insufficient and more needs to be done. For example, the first diagnosis can easily be missed due to inadequate health worker knowledge or absence of diagnostic materials, and median HbA1c values of 9.5% after 6–8 years of treatment are well above target values in high-income countries. A large proportion of children and youth are not fully stabilized and continue to suffer from higher levels of acute and chronic complications than fully stabilized children in high-income countries, although these have become less frequent; their school attendance and performance are not optimal.

Insulin donation programmes can lead to changes in national health systems

In 2013, an independent evaluation of LFAC [15] concluded that the country programmes have led to better training, more free care, and health systems that are better able to deal with diabetes. Experience in a small number of countries suggests that this is indeed the case. In 2017, the government of Tanzania took over the procurement and supply of insulin and established a special unit for non-communicable diseases in the Ministry of Health, with six staff. Diabetes prevention and care in Tanzania is increasingly being integrated with clinics for HIV, tuberculosis, leprosy, dental care, and nutrition [22]. Such experiences can serve as an example for the many LMIC that still depend on insulin donations.

Public reporting is scattered, incomplete, and sometimes inconsistent

The level of reporting on the support programmes varies greatly between companies, programmes, countries, and years. When insulin donations are mentioned, the types and quantities are rarely specified. When the value of insulin donations

are disclosed, it is not clear whether the amounts are based on retail sale prices in OECD countries, or on international not-for-profit whole-sale prices as required by WHO [34]. Only in recent years have an increasing number of papers and conference presentations described the magnitude and health benefits of support programmes. The scientific quality of these papers is not very high: none had a control group, many were simple 'pre-post' studies, and the rest were 'post-only'. This lack of scientific rigour is consistent with a recent systematic review of company reports on the impact of 'access' programmes, which found that 62% of evaluations were of low and 32% were of very low quality [35].

Are insulin donation programmes sustainable?

The rising number of surviving young adults with type 1 diabetes in the countries with effective donation and support programmes now creates a sustainability challenge. There are two aspects to this: the sustainability of diabetes care and prevention of complications for patients surviving and 'aging out' of the donation programmes (19/21 years of age for CDiC or 25 years for LFAC)—called 'transition'; and the continuation of the financial support, including insulin donations, to the programmes in general.

In the LFAC evaluation, 31 (78%) of country programmes indicated that they cannot support individuals through the transition [15]. In response, several countries, such as Bangladesh, Tanzania, and Rwanda, have initiated specific activities to empower the surviving young adults to earn a living and look after themselves. These activities seem to be at least partly successful, but they are not yet part of all country programmes. With regard to programme sustainability, there are no signals that the major donors are considering withdrawal of their support. Novo Nordisk recently extended the CDiC programme beyond its original target date and expanded into five new countries (Cambodia, Ivory Coast, Myanmar, Senegal, and Sudan). Eli Lilly committed itself to insulin donations to the LFAC programme till 2019. There are currently no indications of a change in donor attitude.

And yet donation programmes, essential as they can be in certain situations, can never offer a permanent solution. For the patients and their families, free insulin is probably the most visible aspect of the support programme; it may even be the main reason for them to visit the clinic at all. However, the cost of insulin represents only one quarter of total supply costs (including also syringes, the glucose meter and strips, and HbA1c testing) [36]. Free insulin has been an essential condition for success; but it is not sufficient and must be placed alongside many other essential supplies. And supplies are only part of diabetes care and prevention of complications; equally essential are health professional education, public awareness, and psychosocial support.

In our view, the only sustainable future towards universal access in LMIC is inclusion of standard diabetes care and prevention in national health insurance or social security programmes. Life-long treatment of chronic life-threatening diseases, such as diabetes, should be the highest priority when countries are establishing such schemes,

because in these cases out-of-pocket payments for the treatment and the risk of serious complications have a great potential to cause catastrophic health expenditure for uninsured patients and their families. As long as such schemes do not exist or only offer coverage to part of the population, insulin donation programmes can serve a very important purpose, leading to great health benefits to individual patients and their families, and contributing to population health as a whole.

To facilitate the change from donation programmes to national health systems, we present a first outline of a ten-step process towards a fully sustainable national programme for diagnosis and treatment of diabetes type 1 and the prevention and treatment of its complications (Box 1). This proposal is largely based on the experiences of some donation programmes described above, and especially on the progress being made in Tanzania. It builds on the increasing visibility, status, and reputation of these programmes with national health policy makers, and on the empowerment of health care workers and patients. We acknowledge that it can never cover all complexities of national programmes and the many differences between countries. Yet, in countries where the donor-supported programme has reached near-national coverage, the managers and diabetes specialists of these programmes have often established good contacts with the national government and are now in a position to propose a step-by-step transfer of responsibility. This is especially relevant at the time when a government is moving towards universal health coverage through national health insurance or social security schemes. In these countries, our ten-step process may serve as a basis for a plan of action for the government, and as a perspective for the national NGO and external donors; it could also serve as a yardstick to measure progress.

A final word about the role of the pharmaceutical industry. The fact that only three companies produce 92–93% of all insulin consumed in the world [3] creates a virtual monopoly that allows them to maintain high prices in most countries (or even increasing them, as in the USA), with very little room for competition by generic or biosimilar products. In the 2018 Access to Medicine Index, Eli Lily is ranked in 20th (lowest) position, with below-average scores on product donations and equitable pricing, reaching only one quarter of target countries. Novo Nordisk is in 6th place, with high scores on product donations and capacity building, but not doing very well on patents and pricing.

The positive impact of donation programmes to a relatively small number of poor and disadvantaged patients in LMIC, as described above, is in itself no reason for the global public health community not to expect, or demand, from the pharmaceutical industry a system of equitable pricing policies as well. For example, lower insulin prices for national governments and social health insurance systems in LMIC, through intra-country differential pricing, would facilitate the inclusion of essential insulin products in the basic health care package for all citizens, probably removing the need for donations altogether.

Box 1. Ten steps to phase out an insulin donation programme

(1) In countries where the public sector is unable to provide insulin and where high prices in the private sector make insulin unaffordable, the pharmaceutical industry and other donors should support a national diabetes programme with a free basic package of patient education, diagnosis, and treatment for as many children and youth with type 1 diabetes as possible, thereby preventing the almost certain death they would otherwise face; and create a national patient register for follow-up and reporting.

(2) The pharmaceutical industry and other donors should collaborate with the national diabetes programme to create a national continuum of care for type 1 diabetes from childhood to early adulthood, e.g. by combining in every eligible country the CDiC donation programme (till age 18), the LFAC donation programme (till age 25), and the Base of the Pyramid and other insulin discount programmes (for adults).

(3) The national diabetes programme should collaborate with the Ministry of Health to strengthen national health systems to prevent, diagnose, and treat acute and chronic complications of type 1 diabetes, e.g. by creating diabetes clinics in every district hospital.

(4) Donors and the national diabetes programme should provide detailed information on key aspects of the support programme, such as the number and basic characteristics of recipient patients; the number, type, and value of diagnostic tests and medicines donated; the nature and cost of other programme activities supported; and basic health outcomes such as mortality, weight gain, mean HbA1c levels, and frequency of complications.

(5) The national diabetes programme should deliver to the Ministry of Health, national health insurance systems, and donors the proof of concept that type 1 diabetes can successfully and cost-effectively be diagnosed and treated in LMIC, with improved health outcomes for patients.

(6) The national diabetes programme should support the Ministry of Health in developing and implementing a national diabetes policy and implementation plan, as a public commitment and guide for action towards achieving universal access to decentralized health services for the prevention, diagnosis, and treatment of diabetes, as part of the progressive realization of the right to health.

(7) The national diabetes programme should encourage the government to include the diagnosis, care and treatment of diabetes in all social health insurance programmes.

(8) The pharmaceutical industry should create or strengthen intra-country differential pricing mechanisms to make essential insulin products affordable to national governments and social health insurance schemes.

(9) The national diabetes programme should encourage the Ministry of Health to integrate the prevention, diagnosis, and treatment of diabetes and its complications with the delivery of nutritional advice and with services for

the prevention and treatment of other chronic conditions such as HIV, tuberculosis, leprosy, and hypertension.

(10) The pharmaceutical industry and other donors should phase out their support to the national diabetes programme as soon as these objectives have been achieved.

Conclusion

Over the last decade, support programmes with a component of insulin donation have delivered the proof of concept that, contrary to common belief, diagnosis and treatment of type 1 diabetes and the prevention of debilitating and fatal complications in children are practically possible in low- and middle-income countries. Continued donor support is justified by the individual health benefits achieved, by the contribution towards population health, by the valuable health system experience with early diagnosis and treatment of type 1 diabetes in LMICs, and by the learning opportunities offered by the future transition of donor-supported programmes into comprehensive NCD services.

Even so, donations can never offer a sustainable solution. Sufficient evidence has now been generated to start in earnest a discussion with national governments on the inclusion of standard diabetes care in social security or health insurance schemes. The pharmaceutical industry should support this development by using their monopoly position to make essential insulin products affordable to national governments and social health insurance schemes, through intra-country differential pricing. Preventing certain death and increasing the quality of life for the children of today by the regular supply of insulin is a real contribution towards population health of tomorrow. Social justice demands nothing less.

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Compliance with ethical standards

Conflict of interest The authors do not have any financial or other relation with the pharmaceutical companies concerned. Staff members of the pharmaceutical companies and foundations have commented on an early version of the study but had no influence on the contents of the final report. HVH reports personal fees from the World Health Organization, Health Action International, and the Access to Medicine Foundation, outside the submitted work. SR declares no competing interests.

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